

APRIL 2020

Beyond Medicines in Ukraine

Takeda

Submitted as part of Access Accelerated

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The information in this report has been submitted by the company concerned to the Access Observatory at Boston University. The information will be updated regularly. For more information about the Observatory go to www.accessobservatory.org

The information contained in this report is in the public domain and should be cited as: Takeda, Beyond Medicines in Ukraine (2020), Access Observatory, Boston, US 2020 (online) available from www.accessobservatory.org

Program Description

Program Overview

1 Program Name

Takeda, Beyond Medicines in Ukraine

2 Diseases program aims to address

- Cancer (Hematological)

3 Beneficiary population

- Age Group: All ages
- Gender: All genders
- Special Populations: General population, People with low income

4 Countries

- Ukraine

5 Program start date

September 1, 2016

6 Anticipated program completion date

Completion date not specified

7 Contact person

Susanne Weissbaecker: Susanne.Weissbaecker@takeda.com

8 Program summary

The objectives of the program are (1) to improve access to diagnostic procedures for relapsed and refractory Hodgkin's lymphoma patients, and (2) to support the ongoing professional development of pathologists and clinicians who diagnose and treat lymphoma and (3) provide patient education.

Specifically, the program covers the costs for PET-CT scans, an expensive diagnostic procedure that is not covered by the government or health insurance. It also covers the costs of immunohistochemistry which is a valuable clinical tool for assessing CD30+ patients who may respond to treatments such as Adcetris® that target the CD30 protein. The program has been extended for 2019, and since September 2016 when the program was launched approximately 200 PET-CT scan tests and 300 CD30+ tests have been subsidized.

The program also provides for:

- the professional development of pathologists, for example, seminars where difficult diagnostic cases are discussed, links between pathologists and clinicians are strengthened, and web-based resources for pathologists are created. Since program launch approximately 100 pathologists have been trained through this initiative.
- Hodgkin's lymphoma tutorials for clinicians (Hematologists and oncologists) in the major cities of Ukraine and since the program launch, over 100 clinicians have been trained. Finally,
- training programs for nurses, and six programs have been delivered to date in major cities across the Ukraine, with more than 200 nurses trained.
- Patient education seminars, which take place during World Lymphoma Awareness day (15 September).

These elements are delivered by the National Cancer Institute of Ukraine.

URL: <http://www.accessaccelerated.org/initiative/beyond-medicines-strengthening-diagnosis-treatment-lymphoma-ukraine/>

Program Strategies & Activities

9 Strategies and activities

Strategy 1: Community Awareness and Linkage to Care

ACTIVITY	DESCRIPTION
Communication	Patient education seminars are held in different cities across the Ukraine during World Lymphoma Awareness day.

Strategy 2: Health Service Strengthening

ACTIVITY	DESCRIPTION
Training	Providing training on Hodgkin's Lymphoma to pathologists and clinicians.

Strategy 3: Health Service Delivery

ACTIVITY	DESCRIPTION
Diagnosis	Subsidizing the cost of diagnostic tests for Hodgkin's lymphoma.

10 Strategy by country

STRATEGY	COUNTRY
Community Awareness and Linkage to Care	Ukraine
Health Service Strengthening	Ukraine
Health Service Delivery	Ukraine

Companies, Partners & Stakeholders

11 Company roles

COMPANY	ROLE
Takeda	Planning, monitoring, and evaluating the program in partnership with the National Cancer Institute of Ukraine and other partners, and funding the program.

12 Funding and implementing partners

PARTNER	ROLE/URL	SECTOR
National Cancer Institute of Ukraine - Hematology Department	Coordination of program activity, scientific support, presentations for clinicians and pathologists. http://unci.org.ua/en/institute/about	Public
Diagnostic Center Feofaniya	PET-CT scans. http://feofaniya.org	Public
CSD Healthcare Clinic	Immunohistochemistry testing. http://csdclinic.com.ua/uk	Private
Cherkasky Onco Dispenser Patient Association	Patient education, logistics.	Voluntary
Medical Data Management (MDM)	Logistic partner http://mdmworld.com/	Private

Companies, Partners & Stakeholders

13 Funding and implementing partners by country

PARTNER	COUNTRY
National Cancer Institute of Ukraine - Hematology Department	Ukraine
Diagnostic Center Feofaniya	Ukraine
CSD Healthcare Clinic	Ukraine
Cherkasky Onco Dispenser Patient Association	Ukraine
Medical Data Management (MDM)	Ukraine

14 Stakeholders

STAKEHOLDER	DESCRIPTION OF ENGAGEMENT	REQUESTED OR RECEIVED FROM STAKEHOLDER
Non-governmental organization (NGO)	We are engaging with NGOs to provide patient education and manage some program logistics (appointments, scheduling etc).	Infrastructure: No Human Resources: Yes Funding: Yes Monitoring or Oversight: Yes Other resource: Yes
Commercial Sector	We are working with the commercial sector to manage patient databases and schedule appointments.	[No response provided]
Local Hospitals/ Health Facilities	We are working with local hospitals for providing PET/CT scans and lab tests	Infrastructure: Yes Human Resources: Yes Funding: No Monitoring or Oversight: Yes Other resource: Yes

Local Context, Equity & Sustainability

15 Local health needs addressed by program

This program addresses the lack of affordability of PET/CT scans and CD30+ tests needed for diagnosis of Hodgkin’s lymphoma among low income people in Ukraine, where moderate poverty has increased from 15% in 2014 to 22% in 2015, and the poverty rate (income under \$5 per day in 2005 PPP) has increased from 3.3% to 5.8% during the same period.¹

Due to inadequate access to diagnostics in Ukraine, 65.2% of newly diagnosed Hodgkin’s lymphoma patients in 2015 had late stages (stages III or IV) of the disease.²

a How needs were assessed

The local Takeda office together with our partners identified the need.

b Formal needs assessment conducted

No.

16 Social inequity addressed

Yes. This program seeks to improve the affordability of diagnostic procedures and lab tests for low income people in Ukraine by covering the costs for PET-CT scans and CD30+ immunohistochemistry that are expensive diagnostic procedures which are not covered by the government or health insurance.

17 Local policies, practices, and laws considered during program design

POLICY, PRACTICE, LAW	APPLICABLE TO PROGRAM	DESCRIPTION OF HOW IT WAS TAKEN INTO CONSIDERATION
National regulations	[No response provided]	
Procurement procedures	[No response provided]	
Standard treatment guidelines	[No response provided]	
Quality and safety requirements	[No response provided]	
Remuneration scales and hiring practices	[No response provided]	
Other, please specify	Yes	<p>The program was created because universal health care is currently unavailable in Ukraine (almost every diagnostic procedure and medicine must be paid for out-of-pocket), and some medical specialties lack a system for continuous education.</p> <p>We have partnered with the National Cancer Institute of Ukraine to provide continuous medical education on Hodgkin’s Lymphoma. Our partner ensures that the curriculum and content of the tutorials for clinicians and the web-based resources for pathologists are consistent with local regulations for physicians’ continuous medical education. Additionally, the PET-CT scans and immunohistochemistry testing that we provide free to qualifying patients are done in accredited laboratories that meet local and international standards.</p>

18 How diversion of resources from other public health priorities are avoided

This program is contributing to delivering against public health priorities.

19 Program provides health technologies (medical devices, medicines, and vaccines)

No.

20 Health technology(ies) are part of local standard treatment guidelines

N/A.

21 Health technologies are covered by local health insurance schemes

N/A.

22 Program provides medicines listed on the National Essential Medicines List

N/A.

23 Sustainability plan

We are in the process of developing a transition plan with a view to attracting other sponsors for maintaining or expanding this program into other hematological cancers, and seeking partial government support.

Additional Program Information

24 Additional program information

No additional information provided.

a Potential conflict of interest discussed with government entity

No.

25 Access Accelerated Initiative participant

Yes.

26 International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) membership

Yes.

Resources

- 1 The World Bank. Ukraine Economic Update - April 2017, accessed from <http://www.worldbank.org/en/country/ukraine/publication/economic-update-spring-2017>
- 2 The National Cancer Institute of Ukraine, 2017. Bulletin of National Cancer Registry of Ukraine 2015-2016, accessed from http://www.ncru.inf.ua/publications/BULL_18/PDF_E/60-61_hodg.pdf

Program Indicators

PROGRAM NAME

Beyond Medicines in Ukraine

27 List of indicator data to be reported into Access Observatory database

INDICATOR	TYPE	STRATEGY	2017	2018	2019
1 Staff time	Input	All Program Strategies	---	---	---
2 Value of resources	Input	All Program Strategies	---	---	---
3 Number of patients tested	Output	Health Service Delivery	---	---	---
4 Number of people trained	Output	Health Service Strengthening	---	---	---
5 Health provider knowledge	Outcome	Health Service Strengthening	---	---	---
6 Number of patients treated by physicians trained by program	Outcome	Health Service Strengthening	---	---	---

INDICATOR **Staff time**

STRATEGY ALL PROGRAM STRATEGIES

ITEM	DESCRIPTION
Definition	The ratio of the total number of paid hours during a year by the number of working hours in that period. This indicator excludes the time of volunteers or staff time for external partners.
Method of measurement	The ratio is also called Full Time Equivalent (FTE) CALCULATION: $\frac{\text{Sum of the number of paid hours per year}}{\text{Total number of working hours per year}}$
28 Data source	Routine Program Data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Company	The staff from Takeda working on this program track the number of hours spent working on the program.	Once per year
31 Data processing	Company	Staffs who are responsible for the management of the program will use the data of staff time spent on the program to calculate the Full Time Equivalent (the ratio of the total number of paid hours during a year by the number of working hours in that period).	Once per year
32 Data validation		Once the data is reported to the Access to Medicines office, the staff responsible for the program conducts a sanity check on the submitted data.	

33 Challenges in data collection and steps to address challenges

[No response provided.]

INDICATOR	2017	2018	2019
1 Staff time	---	---	---

Comments: N/A

ITEM	DESCRIPTION
Definition	Total expenditure by company to operate program, including all expenditures that can reasonably be defined as necessary to operate the program
Method of measurement	Program administrative records or accounting or tax records provide details in the expenditures on the program in a defined period of time CALCULATION: Sum of expenditures (e.g., staff, materials) on program in US\$
28 Data source	Routine program data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Company	Data are collected from finance and accounting department expenditure records. A member of the program team submits invoices to finance and accounting to be paid. Finance makes the payments and keeps records of payments.	Once per year
31 Data processing	Company	Staffs who are responsible for the management of the program produce a financial report based on the Program administrative and accounting records. The expenses for the year are summed at the end of the year.	Once per year
32 Data validation		Financial reports are audited based on program receipts.	

33 Challenges in data collection and steps to address challenges

[No response provided.]

INDICATOR	2017	2018	2019
2 Value of resources	---	---	---

Comments: N/A

INDICATOR **Number of patients tested**

STRATEGY HEALTH SERVICE DELIVERY

3

ITEM	DESCRIPTION
Definition	Number of patients that have received diagnostic test through the program
Method of measurement	Counting of people who received diagnostic test through the program CALCULATION: Sum of the number of people tested
28 Data source	Routine Program Data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Company	The diagnostic centers keeps a record of patients tested through the program. Staff who are responsible for the management of the program collect the data from the diagnostic centers and report by email to the Access to Medicines office.	Once per year
31 Data processing	Company	Staffs who are responsible for the management of the program sum up the number of patients tested each year based on the data from partners and report by email to the Access to Medicines office.	Once per year
32 Data validation		Takeda Access to Medicines office conducts a sanity check once the data is submitted by the project team based in Ukraine.	

33 Challenges in data collection and steps to address challenges

[No response provided.]

INDICATOR	2017	2018	2019
3 Number of patients tested	---	---	---

Comments: N/A

ITEM	DESCRIPTION
Definition	Number of trainees
Method of measurement	Counting of people who completed all training requirements CALCULATION: Sum of the number of people trained
28 Data source	Routine Program Data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Company	Staffs who are responsible for the management of the program maintain an attendance sheet for all training sessions.	Once per year
31 Data processing	Company	Staff who are responsible for the management of the program review the number of attendees per training session and sums up the total number of people who attended each type of training over the past one year.	Once per year
32 Data validation		Takeda staffs who are responsible for the program conduct a sanity check of the data submitted by the implementation partners.	

33 Challenges in data collection and steps to address challenges

[No response provided.]

INDICATOR	2017	2018	2019
4 Number of people trained	---	---	---

Comments: N/A

ITEM	DESCRIPTION
Definition	Percentage of providers that pass the assessment examining their skills or knowledge. The exam should be designed to assess the possession of the skills and knowledge to be able to comply with predefined standards
Method of measurement	The assessment of possession of skills and knowledge occurs through a written, oral, or observational assessment that all providers have to undergo CALCULATION Number of providers who pass the assessment? Number of providers trained
28 Data source	Routine Program Data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Company	A knowledge questionnaire is completed before and after each training session by each health provider attending the training. The questionnaire is marked by a member of the local team based on the correct answers provided by the specialists. The scores are then recorded.	Once per year
31 Data processing	Company	The staff responsible for the program review the post-training survey score and note the number of participants who scored above a pre-determined pass mark. The proportion of participants who scored above the pass mark is then calculated.	Once per year
32 Data validation		Staffs of Takeda conduct a sanity check once the data is before reporting the data into the Access Observatory.	

33 Challenges in data collection and steps to address challenges

[No response provided.]

INDICATOR	2017	2018	2019
5 Health provider knowledge	---	---	---

Comments: N/A

INDICATOR **Number of patients treated by physicians trained by program**

6

STRATEGY HEALTH SERVICE STRENGTHENING

ITEM	DESCRIPTION
Definition	Number of patients that have received treatment for specific diseases through physicians trained by program on management of those specific diseases
Method of measurement	Counting of people who received treatment for specific diseases through physicians trained by program on management of those specific diseases CALCULATION: Sum of the number of people who received treatment for specific diseases through physicians trained by program on management of those specific diseases
28 Data source	Non-Routine Program Data
29 Frequency of reporting	Once per year

	RESPONSIBLE PARTY	DESCRIPTION	FREQUENCY
30 Data collection	Company	The diagnostic centers keeps a record of patients diagnosed with CD30+ Hodgkin Lymphoma. Staff who are responsible for the management of the program collect the data from the diagnostic centers and report by email to the Access to Medicines office.	Every three months
31 Data processing	Company	Staffs who are responsible for the management of the program sum up the number CD30+ Hodgkin Lymphoma patients diagnosed each year based on the data from partners and report by email to the Access to Medicines office.	Every three months
32 Data validation		Staffs of Access to Medicines office conduct a sanity check of the data before submitting it to the Access Observatory.	

33 Challenges in data collection and steps to address challenges

[No response provided.]

INDICATOR	2017	2018	2019
6 Number of patients treated by physicians trained by program	---	---	---

Comments: N/A

Appendix

This program report is based on the information gathered from the Access Observatory questionnaire below.

Program Description

PROGRAM OVERVIEW

1 Program Name

2 Diseases program aims to address:

Please identify the disease(s) that your program aims to address (select all that apply).

3 Beneficiary population

Please identify the beneficiary population of this program (select all that apply).

4 Countries

Please select all countries that this program is being implemented in (select all that apply).

5 Program Start Date

6 Anticipated Program Completion Date

7 Contact person

On the public profile for this program, if you would like to display a contact person for this program, please list the name and email address here (i.e. someone from the public could email with questions about this program profile and data).

8 Program summary

Please provide a brief summary of your program including program objectives (e.g., the intended purposes and expected results of the program; if a pilot program, please note this). Please provide a URL, if available. Please limit replies to 750 words.

PROGRAM STRATEGIES & ACTIVITIES

9 Strategies and activities

Based on the BUSPH Taxonomy of Strategies, which strategy or strategies apply to your program (please select all that apply)?

10 Strategy by country

If you have registered one program for multiple countries, this question allows you to provide a bit more specificity about each country (e.g. some countries have different strategies, diseases, partners, etc.). Please complete these tables as applicable. For each portion you have you selected from above (program strategies), please identify which country/countries these apply.

COMPANIES, PARTNERS AND STAKEHOLDERS

11 Company roles

Please identify all pharmaceutical companies, including yours, who are collaborating on this program:

What role does each company play in the implementation of your program?

12 Funding and implementing partners

Please identify all funding and implementing partners who are supporting the implementation of this program (Implementing partners is defined as either an associate government or non-government entity or agency that supplements the works of a larger organization or agency by helping to carry out institutional arrangements in line with the larger organization's goals and objectives.)

a. What role does each partner play in the implementation of your program? Please give background on the organization and describe the nature of the relationship between the organization and your company. Describe the local team's responsibilities for the program, with reference to the program strategies and activities. (response required for each partner selected).

b. For each partner, please categorize them as either a Public Sector, Private Sector, or Voluntary Sector partner. (Public Sector is defined as government; Private Sector is defined as A business unit established, owned, and operated by private individuals for profit, instead of by or for any government or its agencies. Generation and return of profit to its owners or shareholders is emphasized; Voluntary Sector is defined as Organizations whose purpose is to benefit and enrich society, often without profit as a motive and with little or no government intervention. Unlike the private sector where the generation and return of profit to its owners is emphasized, money raised or earned by an organization in the voluntary sector is usually invested back into the community or the organization itself (ex. Charities, foundations, advocacy groups etc.))

c. Please provide the URL to the partner organizations' webpages

13 Funding and implementing partners by country

If you have registered one program for multiple countries, this question allows you to provide a bit more specificity about each country (e.g., some countries have different strategies, diseases, partners, etc.). Please complete these tables as applicable. For each portion you have selected from above (funding and implementing partners), please identify which country/countries these apply.

14 Stakeholders

Please describe how you have engaged with any of these local stakeholders in the planning and/or implementation of this program. (Stakeholders defined as individuals or entities who are involved in or affected by the execution or outcome of a project and may have influence and authority to dictate whether a project is a success or not (ex. Ministry of Health, NGO, Faith-based organization, etc.). Select all that apply.

- Government, please explain
- Non-Government Organization (NGO), please explain
- Faith-based organization, please explain
- Commercial sector, please explain
- Local hospitals/health facilities, please explain
- Local universities, please explain
- Other, please explain

LOCAL CONTEXT, EQUITY & SUSTAINABILITY

15 Local health needs addressed by program

Please describe how your program is responsive to local health needs and challenges (e.g., how you decided and worked together with local partners to determine that this program was appropriate for this context)?

a How were needs assessed

b Was a formal need assessment conducted

(Yes/No) If yes, please upload file or provide URL.

16 Social inequity addressed

Does your program aim to address social inequity in any way (if yes, please explain). (Inequity is defined as lack of fairness or justice. Sometime 'social disparities,' 'structural barriers' and 'oppression and discrimination' are used to describe the same phenomenon. In social sciences and public health social inequities refer to the systematic lack of fairness or justice related to gender, ethnicity, geographical location and religion. These unequal social relations and structures of power operate to produce experiences of inequitable health outcomes, treatment and access to care. Health and social programs are often designed with the aim to address the lack of fairness and adjust for these systematic failures of systems or policies.*)

*Reference: The definition was adapted from Ingram R et al. Social Inequities and Mental Health: A Scoping Review. Vancouver: Study for Gender Inequities and Mental Health, 2013.

17 Local policies, practices, and laws considered during program design

How have local policies, practices, and laws (e.g., infrastructure development regulations, education requirements, etc.) been taken into consideration when designing the program?

18 How diversion of resources from other public health priorities are avoided

Please explain how the program avoids diverting resources away from other public health priorities? (e.g. local human resources involved in program implementation diverted from other programs or activities).

19 Program provides health technologies

Does your program include health technologies (health technologies include medical devices, medicines, and vaccines developed to solve a health problem and improve quality of lives)? (Yes/No)

20 Health technology(ies) are part of local standard treatment guidelines

Are the health technology(ies) which are part of your program part of local standard treatment guidelines? (Yes/No) If not, what was the local need for these technologies?

21 Health technologies are covered by local health insurance schemes

Does your program include health technologies that are covered by local health insurance schemes? (Yes/No) If not, what are the local needs for these technologies?

22 Program provides medicines listed on the National Essential Medicines List

Does your program include medicines that are listed on the National Essential Medicines List? (Yes/No) If not, what was the local need for these technologies?

23 Sustainability plan

If applicable, please describe how you have planned for sustainability of the implementation of your program (ex. Creating a transition plan from your company to the local government during the development of the program).

ADDITIONAL PROGRAM INFORMATION

24 Additional program information

Is there any additional information that you would like to add about your program that has not been collected in other sections of the form?

a Potential conflict of interest discussed with government entity

Have you discussed with governmental entity potential conflicts of interest between the social aims of your program and your business activities? (Yes/No) If yes, please provide more details and the name of the government entity.

25 Access Accelerated Initiative participant

Is this program part of the Access Accelerated Initiative? (Yes/No)

26 International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) membership

Is your company a member of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)? (Yes/No)

Program Indicators

INDICATOR DESCRIPTION

27 List of indicator data to be reported into Access Observatory database

For this program, activities, please select all inputs and impacts for which you plan to collect and report data into this database.

28 Data source

For this indicator, please select the data source(s) you will rely on.

29 Frequency of reporting

Indicate the frequency with which data for this indicator can be submitted to the Observatory.

30 Data collection

- a. Responsible party: For this indicator, please indicate the party/parties responsible for data collection.
- b. Data collection — Description: Please briefly describe the data source and collection procedure in detail.
- c. Data collection — Frequency: For this indicator, please indicate the frequency of data collection.

31 Data processing

- a. Responsible party: Please indicate all parties that conduct any processing of this data.
- b. Data processing— Description: Please briefly describe all processing procedures the data go through. Be explicit in describing the procedures, who enacts them, and the frequency of processing.
- c. Data processing — Frequency: What is the frequency with which this data is processed?

32 Data validation

Description: Describe the process (if any) your company uses to validate the quality of the data sent from the local team.

33 Challenges in data collection and steps to address challenges

Please indicate any challenges that you have in collecting data for this indicator and what you are doing to address those challenges.

